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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/674,296 | 09/29/2003 | Ronan Thornton | P1818 US (2650/106) | 4107 |

7590 08/15/2006

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| EXAMINER | |
|---|---|
| PRONE, CHRISTOPHER D | |
| ART UNIT | PAPER NUMBER |
| 3738 | |

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/674,296 | THORNTON ET AL. | |
| | Examiner | Art Unit | |
| | Christopher D. Prone | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21,25-31,35,37,38 and 40-47* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-21,25-31,35,37 and 40-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-25 and 28-38 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,380,299 Fearnot.

In regards to claims 17, 25, 40, 44, Fearnot discloses the same invention being a catheter described in column 1 on lines 11-21 and a drug-polymer coated stent, comprising: a stent framework referenced as element 12, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a first therapeutic agent and a first polymer, which is inherently cured by one of thermal activation, electrical activation, or ionizing irradiation (figure 5) (2:10-25 of Fearnot). Fearnot further discloses thin diffusion barrier layers positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer and a second therapeutic agent shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claims 18, 19, 28, and 29, Fearnot discloses the same invention wherein the stent framework comprises a metallic base made of nitinol described in column 3 on lines 7-22.

In regards to claims 20, 24, 30, and 34, Fearnot discloses the same invention wherein the first and second therapeutic agents are selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof described in column 1 on lines 60-68 of Fearnot.

In regards to claims 21 and 31, Fearnot discloses the same invention wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile described in column 2 on lines 18-22 of Fearnot.

In regards to claims 35 and 47 Fearnot discloses the same invention comprising a drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include at least one therapeutic agent and a cured first polymer described in column 2 in lines 10-25; wherein it is inherent that the invention of Fearnot comprises inserting a drug-polymer coated stent within a vessel of a body and eluting at least one therapeutic agent from the laminated drug-polymer coating into the body. Fearnot further discloses thin diffusion barrier layers positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer and a second therapeutic agent shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 36, Fearnot discloses the same invention wherein the drug-polymer coated stent includes at least one thin barrier layer positioned between one or

more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 37, Fearnot discloses the same invention wherein the thin barrier layers control an elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

In regards to claim 38, Fearnot discloses the same invention comprising selecting the cured first polymer and the cured second polymer based on a predetermined elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

In regards to claims 41, 43, and 45, Fearnot discloses the same invention comprising a layer comprising a silicone polymer (3:7-22) and a primer coating on he surface of the stent framework (1:65-68).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,380,299 Fearnot in view of United States Patent 6,251,136 Guruwaiya.

Fearnot discloses the invention substantially as claimed being a catheter and drug-polymer coated stent. However, Fearnot does not disclose use of an inflation balloon and a sheath.

Guruwaiya teaches the use of a balloon catheter with a sheath in the same field of endeavor for the purpose of securing the stent to the catheter during delivery and securing the stent to the operating site after delivery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the sheath and balloon catheter of Guruwaiya with drug-polymer coated stent of Fearnot in order to provide a more secure delivery device for the stent.

Claims 42 and 46 are rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,380,299 Fearnot in view of United States Patent 5,447,724 Helmus et al.

Fearnot discloses the invention substantially as claimed being a catheter and drug-polymer coated stent. However, Fearnot does not disclose use of the amphiphilic copolymer comprising acrylic acid and vinyl pyrollidone.

Helmus teaches the use of a medical implant comprising a coating of amphiphilic copolymer comprising acrylic acid and vinyl pyrollidone in the same field of endeavor for the purpose of metering the delivery of the therapeutic drugs.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the copolymer of Helmus with drug-polymer coated

stent of Fearnot in order to provide a more controlled release of therapeutic drug agents.

### *Response to Arguments*

Applicant's arguments filed 6/12/06 have been fully considered but they are not persuasive. The applicant argues that Fearnot does not disclose the thin barrier layer positioned between the thin drug polymer layers. However, Fearnot discloses a plurality of thin layers, any of which could be considered a thin barrier layer because the more inner layers cannot release until the outer layers are absorbed.

Applicant's arguments with respect to claims 40-47 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

CDP

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER